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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/659,379	09/08/00	VINIK	A 05126.00003

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EXAMINER

ROBINSON, P

ART UNIT

PAPER NUMBER

1653

DATE MAILED:

04/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application N .

09/659,379

Applicant(s)

VINIK ET AL

Examiner

Patricia A. Robinson

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-20 is/are allowed.
- 6) ☒ Claim(s) 21-47 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in regard to what the sequence of INGAP is, without a sequence there is no way to determine the structure or function of INGAP, thus the claims as written are indefinite.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 23 and 24-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making an expression construct with using SEQ ID NO: 6, does not reasonably provide enablement for all expression constructs that produce Islet Neogenesis Associated Protein (INGAP). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims of the issued patent are limited to and only enabled for SEQ ID NO: 6 and 4. Thus, this is an improper broadening of scope. In addition, these claims were specifically amended in the parent application 08/741,096 (ABN) on which 08/909,725 (Patent No. 5,804,421) claims priority as a continuation. Thus, this attempt to broaden back to the original scope is a clear case of recapture and is prohibited.

In addition, claim 21 contains no sequence reference and thus is also too broad.

In *In re Wands*, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification only teaches two polynucleotides, SEQ ID NO: 4 and 6, but the claims are also drawn to SEQ ID NO: 4 variants which encompasses thousands of sequences. The specification does not provide any examples of methods that may be used to determine the critical percent identity that must be maintained in making these conservative substitutions and retain the desired function. The specification also does not give any guidance concerning structural or functional parameters/features the polypeptides must retain that would allow a one skilled in the art to identify them as OFQ receptors.

Based on the specification, these are novel proteins, as evidenced by the statement "[S]pecifically disclosed therein are nucleic acids encoding the novel

mammalian receptor gene." (p.2, last sentence). The novelty of proteins is further evidenced by an absence in the prior art of SEQ ID NO: 4, nor does the prior art teach a particular or common structure or functional feature that can be used to identify these molecules. Therefore, with assistance from the prior art one skilled in the art must rely wholly on the teachings in the instant specification to enable all of the molecules encompassed in the claims.

As taught by Burgess (J. Cell Biology 111:2129 [1990]) recombinant technology and amino acid sequences in particular are highly unpredictable, as witnessed by the fact that the replacement of a single lysine residue at position 132 of heparin-binding growth factor-1 leads to a substantial loss of target binding and biological activity. (See pp. 2132-2133). There is an inverse relationship in regard to level of unpredictability in the art and the amount of guidance and direction necessary for to enable claims with such a broad scope as in the instant case.

Thus, the specification fails to enable the claim commensurate with scope and the claim is therefore rejected.

Allowable Subject Matter

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: claims 19 and 20 appear to fall within the scope of the allowed claim 1 from application 08/909,725.

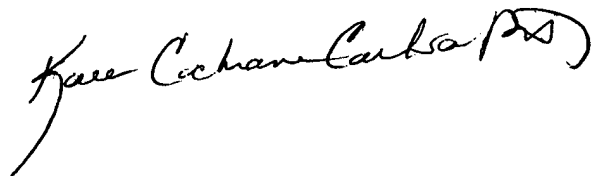
Conclusion

Claims 21-47 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Robinson whose telephone number is 703-305-0096. The examiner can normally be reached on 8:00 - 4:30 Monday - Friday, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, reading "Karen Cochrane Carlson" followed by a stylized monogram or initials.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

PAR
April 9, 2001